Tips for Importing FDA-Regulated Products in ACE

FDA Division of Compliance Systems 2016

Diagram depicts mandatory data elements by commodity-type. For certain products, additional data elements may apply. Refer to FDA's Supplemental Guide for further specificity For more information email: ACE_Support@fda.hhs.gov

Drugs:

Intended Use Code*

Active Ingredient Name(s) & Dosage

Brand Name

Name & Address of API Producer(s), Sponsor (if applicable)

Affirmations of Compliance*

Medical Devices & Radiation-Emitting Products:

Intended Use Code

Brand Name (if available)

Name and Address of Device Initial Importer (medical devices only)

Affirmations of Compliance*

Biologics:

Intended Use Code

Brand or Proper Name (except for cells and tissues)

Affirmations of Compliance*

Required Data Elements for all FDA Products:

Commodity & Subtype

Product Code

Country of Production or Source

Invoice Description

Names & Addresses of Manufacturer, Shipper, Importer, Delivered To Party

Entry Point of Contact

Quantity , Packaging , Line Value

Arrival Date & Time

Animal Drugs & Devices:

Active Ingredient Name(s) & Dosage (drugs only)

Brand Name

Affirmations of Compliance*

Food Products requiring Prior Notice:

Country of Shipment; Place of Growth (if applicable)

Names and Addresses of PN Transmitter, Submitter, Owner, Ultimate Consignee;(in lieu of DP) Grower or Consolidator if Applicable

Contact Information for Transmitter & Submitter

Container Number

Affirmations of Compliance*

Port of Arrival

Tobacco:

Intended Use Code

Submitter

Affirmations of Compliance*

**DUNS or FEI numbers are not mandatory but are highly encouraged and may expedite processing.

*Affirmations of Compliance are mandatory in some instances but are not required for all scenarios. Cosmetics and food contact surfaces do not require any additional data elements other than those listed in the center of the diagram.